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BIOMET MANUFACTURING CORP.

FEB 2 7 2013

510(k) Summary

Preparation Date: 23 October, 2012

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, IN 46582
FDA Registration #: 1825034

Contact Person:
Gary Baker
Sr. Regulatory Specialist
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Proprietary Name: Orthopedic Salvage System (OSS)

Common Name: Constrained knee

Classification Code(s)/Name(s): JDI, KRO

888.3350 (JDI) – Hip joint metal/polymer semi-constrained cemented prosthesis.

888.3510 (KRO) – Knee joint femorotibial metal/polymer constrained cemented prosthesis

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K002757 - Oncology Salvage System (Biomet)

Device Description:
The Orthopedic Salvage System is a system of modular and non-modular components that are intended to be used for difficult revision surgeries or limb salvage procedures. The components can replace any portion of, or the total femur and/or the knee and proximal tibia.

Intended Use:
The Orthopedic Salvage System components are intended for cemented use only unless used in a proximal femoral replacement application.

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Warsaw, IN 46582

Indications For Use:

Biomet's Segmental Femoral Replacement components are intended for use in total knee, total hip, or total femoral replacement procedures. Specific indications are:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.
2. Correction of varus, valgus or post-traumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies.
5. Tumor resections.
6. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.*
7. Revision of previously failed total joint arthroplasty.
8. Trauma.

These devices are to be used with bone cement unless a proximal femur is indicated for use (USA).

*Not applicable to Regenerex Ultra Porous Construct titanium knee augment usage (not licensed in Canada), or any other knee component.

When components of the Orthopedic Salvage System are used with Biomet's Compress Segmental Femoral Replacement System, they are intended for uncemented application and indicated for:

1. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty.
4. Trauma.

Summary of Technologies:
The modifications proposed within this submission include expanding the product line and modifying the male tapers from a machined taper to a roller hardened and machined taper.

Non-Clinical Testing:
Cantilever Fatigue testing was conducted to evaluate the taper cantilever fatigue strength and compare the results with the cantilever fatigue strength of the predicate tapers. Results determined that the roller hardened tapers were stronger in cantilever fatigue than the predicate tapers. The acceptance criteria were met.

Compressive Fatigue testing was conducted to evaluate the taper compressive fatigue strength and compare the results with the compressive fatigue strength of the predicate tapers. Results determined that the compressive fatigue strength of the roller hardened tapers was equivalent to or greater than the compressive fatigue strength of the predicate tapers. The acceptance criteria were met.

Static Axial Separation testing was conducted to evaluate the pull-off strength of the taper junction and compare the results with the pull-off strength of the taper junction of the predicate tapers. Results determined that the pull-off strength of the roller hardened tapers was equivalent to or greater than the pull-off strength of the predicate tapers. The acceptance criteria were met.

Clinical Testing:
Clinical testing was not required to demonstrate substantial equivalence of the design modifications proposed to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2013

Biomet Manufacturing Corp.
% Mr. Gary Baker
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K123501
Trade/Device Name: Orthopedic Salvage System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, KRO
Dated: January 11, 2013
Received: January 28, 2013

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123501

Device Name: Orthopedic Salvage System

Indications for Use:
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1. *Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.*
2. *Tumor resections.*
3. *Revision of previously failed total joint arthroplasty.*
4. *Trauma.*

Prescription Use YES AND/OR Over-The-Counter Use NO (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices